Amendments to the Claims

1. (Previously presented) A method for treating peripheral artery disease in a patient, said method comprising administering to said patient a therapeutically effective amount of fibroblast growth factor (FGF), wherein said therapeutically effective amount of FGF is divided into two doses and a single dose is administered into each leg of said patient within a one hour period, whereby said peripheral artery disease is treated.

2. (Original) The method of claim 1, wherein said FGF is administered by intra-arterial infusion (IA) into at least one artery of each leg of said patient.

3. (Original) The method of claim 2, wherein said FGF is administered into the common femoral artery of each leg of said patient.

4. (Original) The method of claim 3, wherein said FGF is administered via bilateral delivery using a catheter.

5. (Original) The method of claim 3, wherein said FGF is administered via direct IA infusion into the common femoral artery of each leg of said patient.

6. (Original) The method of claim 1, wherein said FGF is administered by one or more intramuscular (IM) injections.

7. (Original) The method according to claim 1, wherein said peripheral artery disease is evidenced by claudication.

8. (Original) The method according to claim 7, wherein said patient has critical limb ischemia.

9. (Original) The method of claim 1, wherein said FGF is FGF-2.

10. (Original) The method of claim 9, wherein said FGF-2 is a recombinant molecule.

11. (Previously presented) The method of claim 10, wherein said FGF-2 comprises the sequence set forth in SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8 or an angiogenically active fragment or mutein thereof.

12. (Original) The method of claim 11, wherein said mutein comprises an FGF-2 molecule wherein at least one constituent cysteine residue is replaced by a neutral amino acid.

13. (Original) The method of claim 12, wherein the neutral amino acid is serine or threonine.

14. (Original) The method of claim 11, wherein said FGF-2 is administered simultaneously with another molecule selected from the group consisting of heparin and other proteoglycan.

15. (Original) The method of claim 14, wherein said heparin is a low molecular weight molecule.

16. (Original) The method of claim 14, wherein said heparin is unfractionated heparin.

17. (Currently amended) The method of claim 11, wherein said FGF-2 is administered within about 5 minutes to about 60 minutes of heparin or other proteoglycan administration to said patient.

18. (Original) The method of claim 17, wherein said FGF-2 is administered within about 20 minutes to about 30 minutes of heparin or other proteoglycan administration to said patient.

19. (Original) The method of claim 11, wherein said FGF-2 is administered in the absence of administering a molecule selected from the group consisting of heparin and other proteoglycan.

20. (Original) The method of claim 11, wherein said therapeutically effective amount of FGF-2 is administered to said patient once in a 24 hour period.

21. (Original) The method of claim 11, wherein said therapeutically effective amount of FGF-2 is administered to said patient once a week.

22. (Original) The method of claim 11, wherein said therapeutically effective amount of FGF-2 is administered to said patient once a month, once every 2 months, once every 3 months, once every four months, once every five months, or once every six months.

23. (Original) The method of claim 11, wherein said therapeutically effective amount of FGF-2 is administered as an adjunct to vascular surgery, mechanical bypass surgery, angioplasty, or angiogram.

24. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 0.1 μg/kg to about 1 μg/kg.

25. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 1 μg/kg to about 3 μg/kg.

26. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 3 μg/kg to about 5 μg/kg.

27. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 5 μg/kg to about 7 μg/kg.

28. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 7 μg/kg to about 9 μg/kg.

29. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 9 μg/kg to about 10 μg/kg.

30. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 10 μg/kg to about 15 μg/kg.

31. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 15 μg/kg to about 20 μg/kg.

32. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 20 μg/kg to about 25 μg/kg.

33. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 25 μg/kg to about 30 μg/kg.

34. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 30 μg/kg to about 40 μg/kg.

35. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 40 μg/kg to about 50 μg/kg.

36. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 4 μg to about 0.3 mg.

37. (Original) The method of claim 11, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 0.3 mg to about 3.5 mg.

38. (Original) The method of claim 37, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 1.0 to about 2.0 mg.

39. (Original) The method of claim 37, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 2.0 to about 3.5 mg.

40. (Currently amended) The method of claim 9, wherein said FGF-2 is administered to said patient by intra-arterial (IA) or intravenous (IV) infusion.

41. (Original) The method of claim 9, wherein said FGF-2 is administered to said patient by one or more intramuscular (IM) injections.

42. (Original) The method of claim 9, wherein said FGF-2 is administered to said patient by subcutaneous (SC) injection.

43. (Original) The method of claim 9, wherein said administering of FGF-2 provides an improvement in peak walking time (PWT) in said patient relative to PWT in the absence of said administering of FGF-2.

44. (Original) The method of claim 9, wherein said administering of FGF-2 provides an improvement in anklebrachial index (ABI) in said patient relative to ABI in the absence of said administering of FGF-2.

45. (Original) The method of claim 9, wherein said administering of FGF-2 results in a reduction in body pain.

46. (Original) The method of claim 9, wherein said administering of FGF-2 improves stair climbing ability.

47. (Original) The method of claim 9, wherein said administering of FGF-2 reduces the severity of claudication.

48. (Previously presented) A method for treating peripheral artery disease in a patient, said method comprising administering to said patient a therapeutically effective amount of fibroblast growth factor-2 (FGF-2), wherein said therapeutically effective amount is about 0.1

μg/kg to about 9.9 μg/kg, wherein said therapeutically effective amount of FGF-2 is divided into two doses and a single dose is administered into each leg of said patient within a one hour period, whereby said peripheral artery disease is treated.

49. (Original) The method of claim 48, wherein said therapeutically effective amount of FGF-2 is administered as part of a pharmaceutical composition.

50. (Original) The method of claim 49, wherein said pharmaceutical composition is a stabilized FGF-2-DTT formulation.

51. (Original) The method of claim 48, wherein said FGF-2 is administered simultaneously with another molecule selected from the group consisting of heparin and other proteoglycan.

52. (Original) The method of claim 48, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 0.1 μg/kg to about 1 μg/kg.

53. (Original) The method of claim 48, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 1 μg/kg to about 3 μg/kg.

54. (Original) The method of claim 48, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 3 μg/kg to about 5 μg/kg.

55. (Original) The method of claim 48, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 5 μg/kg to about 7 μg/kg.

56. (Original) The method of claim 48, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 7 μg/kg to about 8 μg/kg.

57. (Original) The method of claim 48, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 8 μg/kg to about 9 μg/kg.

58. (Original) The method of claim 48, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 9 μg/kg to about 9.9 μg/kg.

59. (Original) The method of claim 48, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 7.0 μg to about 0.7 mg.

60. (Original) The method of claim 59, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 9.0 μg to about 0.5 mg.

61. (Original) The method of claim 60, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 0.1 mg to about 0.4 mg.

62. (Original) The method of claim 61, wherein said therapeutically effective amount of said FGF-2 or said angiogenically active fragment or mutein thereof is about 0.1 mg to about 0.2 mg.

63. (Original) The method of claim 48, wherein said FGF-2 is administered to said patient by intra-arterial (IA) or intravenous (IV) infusion.

64. (Original) The method of claim 48, wherein said FGF-2 is administered to said patient by one or more intramuscular (IM) injections.

65. (Previously presented) A method for improving peak walking time in a patient with intermittent claudication, said method comprising administering to said patient a therapeutically effective amount of fibroblast growth factor (FGF), wherein said therapeutically effective amount of FGF is divided into two doses and a single dose is administered into each leg of said patient within a one hour period, whereby said peak walking time is improved.

66. (Original) The method of claim 65, wherein said FGF is FGF-2.

67. (Original) The method of claim 66, wherein said therapeutically effective amount of said FGF-2 is about 0.1 μg/kg to about 1 μg/kg.

68. (Original) The method of claim 66, wherein said therapeutically effective amount of said FGF-2 is about 1 μg/kg to about 3 μg/kg.

69. (Original) The method of claim 66, wherein said therapeutically effective amount of said FGF-2 is about 3 μg/kg to about 5 μg/kg.

70. (Original) The method of claim 66, wherein said therapeutically effective amount of said FGF-2 is about 5 μg/kg to about 9 μg/kg.

71. (Original) The method of claim 66, wherein said therapeutically effective amount of said FGF-2 is about 9 μg/kg to about 10 μg/kg.

72. (Original) The method of claim 66, wherein said therapeutically effective amount of said FGF-2 is about 10 μg/kg to about 20 μg/kg.

73. (Original) The method of claim 66, wherein said therapeutically effective amount of said FGF-2 is about 20 μg/kg to about 30 μg/kg.

74. (Previously presented) A method for improving ankle-brachial index in a patient with intermittent claudication, said method comprising administering to said patient a therapeutically effective amount of fibroblast growth factor (FGF), wherein said therapeutically effective amount of FGF is divided into two doses and a single dose is administered into each leg of said patient within a one hour period, whereby said ankle-brachial index is improved.

75. (Original) The method of claim 74, wherein said FGF is FGF-2.

76. (Original) The method of claim 75, wherein said therapeutically effective amount of said FGF-2 is about 0.1 μg/kg to about 1 μg/kg.

77. (Original) The method of claim 75, wherein said therapeutically effective amount of said FGF-2 is about 1 μg/kg to about 3 μg/kg.

78. (Original) The method of claim 75, wherein said therapeutically effective amount of said FGF-2 is about 3 μg/kg to about 5 μg/kg.

79. (Original) The method of claim 75, wherein said therapeutically effective amount of said FGF-2 is about 5 μg/kg to about 9 μg/kg.

80. (Original) The method of claim 75, wherein said therapeutically effective amount of said FGF-2 is about 9 μg/kg to about 10 μg/kg.

81. (Original) The method of claim 75, wherein said therapeutically effective amount of said FGF-2 is about 10 μg/kg to about 20 μg/kg.

82. (Original) The method of claim 75, wherein said therapeutically effective amount of said FGF-2 is about 20 μg/kg to about 30 μg/kg.